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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,224	03/27/2002	Steven J. Penner	Heska USNP	2477

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EXAMINER	
MENDEZ, MANUEL A	

ART UNIT	PAPER NUMBER
3763	8

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,224	PENNER ET AL.	
	Examiner	Art Unit	
	Manuel Mendez	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 42-200 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 42-200 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 42-53, drawn to **a kit for intranasal delivery** comprising of a dose, a diluent, the intranasal device comprising of a probe, a dose administrator, and an intranasal probe coupler, wherein the intranasal probe coupler has at least one aperture which communicates between the dose administrator and the intranasal probe, classified in class 206, subclass 364.

II. Claims 53-59, drawn to **an equine intranasal delivery device** comprising a dose administrator, a force application element coupled to the dose administrator, and an equine influenza cold-adapted live virus derived from the strain A/equine/Kentucky/1/91 (H3N8), EIV-P821, EIV-P824, MSV+5 dose responsive to the force application element, classified in class 128, subclass 200.14.

III. Claims 60-67, drawn to a **dose applicator**, a dose application element coupled to the dose administrator, and a dose responsive to the force application element, classified in class 604, subclass 36.

IV. Claims 68-80, drawn to a **method for producing an equine intranasal delivery device** comprising the steps of providing a dose delivery aperture element, coupling an intranasal probe to the dose delivery aperture, joining a flexible dose administrator having a first end and a second end to the intranasal probe by the first end, and coupling a

conformable dose sequestration element having a dose sequestration volume which communicates with the dose delivery aperture element, classified in class 264, subclass 171.12.

V. Claims 81-89, drawn to a **method of equine intranasal delivery** comprising the steps of sequestering a dose within a conformable dose sequestration element, wherein the conformable dose sequestration element separates the dose from a force application element with a volume of a fluid dose propellant; positioning an intranasal probe within a nostril of an equid, sliding the intranasal probe up the nostril of the equid, terminating sliding of the intranasal probe up the nostril, propelling the dose from the conformable dose sequestration element; and delivering the dose onto a target of the equid, classified in class 604, subclass 500.

VI. Claims 90-125, drawn to an **intranasal delivery device** comprising a force application element, a conformable dose sequestration element having a dose sequestration volume sufficiently large to sequester a dose, wherein the conformable dose sequestration element separates the dose from the force application element, and a fluid dose propellant which separates the conformable dose sequestration element from the force application element, classified in class 604, subclass 37.

VII. Claims 126-138, drawn to **method of delivering a dose intranasally**, comprising the steps of sequestering a dose within a dose sequestration element, wherein the dose sequestration element separates the dose from

a force application element with a volume of fluid dose propellant; measuring a volume of fluid dose propellant, wherein the volume is in excess of a minimum delivery volume of the dose; applying force to the volume of the dose propellant; propelling the dose from the interior volume of the dose sequestration element; delivering the dose to a target susceptible to the dose, and expelling a remaining portion of the volume of the fluid dose propellant from the conformable dose sequestration element, classified in class 604, subclass 514.

VIII. Claims 139-172, drawn to **an intranasal dose delivery device** comprising a stream delivery element, a dose delivery aperture element coupled to the stream delivery element, an intranasal probe responsive to the dose delivery aperture, a flexible dose administrator, an intranasal probe coupler having a first end responsive to the intranasal probe and a second end responsive to the flexible dose administrator, a force application element, a force application element coupler having a first end responsive to the flexible dose administrator, and a second end responsive to the force application element, classified in class 604, subclass 264.

IX. Claims 173-189, drawn to **a method of delivering a dose intranasally**, comprising the steps of establishing a dose in a volume of diluent within a flexible administrator, positioning the flexible administrator within a nostril of the animal, applying force to the dose in the volume of diluent,

propelling the dose in the volume of diluent from a stream delivery element; and streaming the dose in the volume of diluent onto a target susceptible to the dose, classified in class 128, subclass 898.

X. Claims 190-200, drawn to an **intranasal delivery device** comprising a dose administrator having a volume, an intranasal probe coupled to the dose administrator, an intranasal probe coupler having a first end responsive to the intranasal probe and a second end responsive to the dose administrator, a force application element coupled to the dose administrator, a coupler element having a first end responsive to the dose administrator and a second end responsive to the force application element, a dose-location coordinate indicator responsive to the flexible dose administrator, and a dose, classified in class 604, subclass 516.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, VI, VIII, and X are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, inventions I, II, III, VI, VIII, and X have separate utility in view of the structural differences disclosed in the groups above. See MPEP § 806.05(d).

Inventions IV, V, VII, and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, each of the different inventions have different modes of

operation and consequentially, different effects. Moreover, Group IV is a method of making an apparatus, classified outside the medical art units at the U.S. Patent and Trademark Office.

Inventions IV and (I, II, III, VI, VIII, and X) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another different process.

Inventions (I, II, III, VI, VIII, X) and (V, VII, and IX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed can be practiced with materially different product.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Manuel Mendez
Primary Examiner
Art Unit 3763

MM